

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING)
PHARMACY, INC. PRODUCTS LIABILITY)
LITIGATION)
_____)

MDL No. 2419
Dkt. No 1:13-md-2419 (RWZ)

THIS DOCUMENT RELATES TO:)

All Cases)
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**TENNESSEE CLINIC DEFENDANTS’
MEMORANDUM OF LAW IN SUPPORT OF THEIR
MOTION TO COMPEL
COMPLETION OF THE DEPOSITION OF DAVID KESSLER, MD
WITH AN ORDER MANDATING DIRECT RESPONSES**

Saint Thomas Outpatient Neurosurgical Center, LLC (“STOPNC”); Howell Allen Clinic, a Professional Corporation; John Culclasure, MD; Debra Schamberg, RN, CNOR; and Vaughan Allen, MD (“Tennessee Clinic Defendants”), move the Court, pursuant to Fed. R. Civ. P. 30 and 37, to compel completion of the deposition of the PSC’s opinion witness, David Kessler, MD, with an Order mandating direct responses to the questions, at the expense of the PSC.

On March 4, 2016, the Defendants attempted to depose Dr. Kessler in San Francisco, California. Through the seven (7) hours of time allowed under Fed. R. Civ. P. 30(d)(1), with an additional fifteen (15) minutes granted by the Plaintiffs at the expiration of seven (7) hours, Dr. Kessler evaded direct responses. His replies to most questions were non-responsive discourses designed to consume time.¹ Not once did counsel for

¹ As shown by the record, on several occasions the witness asked the videographer and court reporter how much time was left. Kessler Dep. 271:20-24.

the PSC instruct the witness to provide direct answers to the Defendants' questions. An additional opportunity to obtain responses from the witness to direct questions is warranted. Sanctions, in the form of cost-shifting to the witness, or the lawyers that engaged him, are appropriate.

LEGAL AUTHORITY

Fed. R. Civ. P. 30(d)(1) directs the Court to "allow additional time...if needed to fairly examine the deponent or if the deponent, another person, or any other circumstance impedes or delays the examination."² Fed. R. Civ. P. 30(d)(2) authorizes the Court to "impose an appropriate sanction—including the reasonable expenses and attorney's fees incurred by any party—on a person who impedes, delays, or frustrates the fair examination of the deponent."³ "There is nothing in the language of [Fed. R. Civ. P. 30(d)(2)] that excludes the deponent from being the person who impedes, delays, or frustrates fair examination."⁴

The Federal Rules "do not permit evasive or uncooperative answers merely because a deponent is dissatisfied with a question," and they do not permit "intentionally prolonging a deposition to further burden the litigation."⁵

A party seeking discovery may move for an order compelling an answer if "a deponent fails to answer a question asked under Rule 30 or 31."⁶ A person's "evasive or incomplete disclosure, answer, or response must be treated as a failure to disclose, answer or respond."⁷ If the motion is granted, "the court **must**, after giving an

² Fed. R. Civ. P. 30(d)(1).

³ Fed. R. Civ. P. 30(d)(2).

⁴ *Carroll v. Allstate Fire & Casualty Ins. Co.*, No. 12-CV-00007, 2014 WL 859238 at *7 (D. Colo. 2014).

⁵ *GMAC Bank v. HTFC Corp.*, 248 F.R.D. 182, 191 (E.D. Pa. 2008).

⁶ Fed. R. Civ. P. 37(a)(3)(B)(i).

⁷ Fed. R. Civ. P. 37(a)(4).

opportunity to be heard, require the party or deponent whose conduct necessitated the motion, the party or attorney advising that conduct, **or both** to pay the movant's reasonable expenses incurred in making the motion, including attorney's fees."⁸

Federal district courts will grant motions to compel and motions for sanctions when a deponent's conduct violates Fed. R. Civ. P. 30.⁹ The failure of an attorney to take remedial steps to curb the deponent's misconduct warrants sanctioning the attorney, too.¹⁰ When an attorney does not intervene to curb the deponent's misconduct, Courts equate the attorney's silence with endorsement and ratification of the deponent's misconduct.¹¹ The attorney's silent endorsement and ratification of the deponent's misconduct is the "functional equivalent of *advising* [the deponent's] conduct."¹²

DR. KESSLER'S VIOLATION OF FED R. CIV. P. 30

Dr. Kessler impeded, delayed, and frustrated the Defendants' effort to examine him. He evaded questions, ignored the directive to provide direct answers, was nonresponsive, and gave long-winded answers to simple, straightforward questions

⁸ Fed. R. Civ. P. 37(a)(5)(A) (emphasis added).

⁹ See, e.g., *GMAC Bank v. HTFC Corp.*, 248 F.R.D. 182 (E.D. Pa. 2008)(granting Plaintiff's motion to compel and motion for sanctions when Defendant deponent continually failed to answer Plaintiff's questions, and, when he did answer questions, provided evasive, uncooperative, and long-winded answers to straightforward questions); *Carroll v. Allstate Fire & Casualty Ins. Co.*, No. 12-CV-00007, 2014 WL 859238 (D. Colo. 2014)(holding that the expert witness deponent's evasive responses impeded Defendant's counsel from gathering information from the expert, warranting the imposition of sanctions); *Luangisa v. Interface Operations*, No. 2:11-cv-00951, 2011 WL 6029880 (D. Nev. 2011)(holding that the deponent's "refusal to answer questions based on his counsel's suggestive, argumentative, and unnecessary objections improperly impeded and frustrated fair examination of [the deponent] during the deposition"); *Van Stelton v. Van Stelton*, No. C11-4045-MWB, 2013 WL 5574566 (N.D. Iowa 2013)(holding that Fed. R. Civ. P. 30(d)(2) sanctions were warranted because the defendants impeded, delayed, and frustrated the plaintiffs' efforts at a fair examination).

¹⁰ *GMAC Bank v. HTFC Corp.*, 248 F.R.D. 182, 197 (E.D. Pa. 2008).

¹¹ *Id.*

¹² *Id.* at 197-98 (emphasis added).

throughout his deposition. The video and full transcript of Dr. Kessler's deposition are submitted with this motion.

Episodically evasive witnesses are not rare. *However*, Dr. Kessler's performance went well beyond that of an experienced opinion witness and advocate, for the party that engaged him, in carefully avoiding direct answers. His performance was a flat refusal, on countless occasions, to even address the question asked. Counsel requests, respectfully, that the Court take the time to watch at least some of the video of the deposition.¹³ It will clearly demonstrate to this Court that the instant motion is well-taken. In this case, the video is (quite literally) worth a thousand words.

The video and transcript demonstrate Dr. Kessler's pervasive, persistent unresponsiveness. However, the following "top 10" list captures Dr. Kessler's method throughout the deposition.¹⁴

1.

Q: You also know that the New England District Office of the FDA did not send that cease and desist order to the Massachusetts Board of Registration and Pharmacy, don't you?

A: I've read Dr. Hamburg's testimony on that. In fact, I have the exact language. Let me tell you what I know. Dr. Hamburg testified she wished there was better communication. The Massachusetts Board of Pharmacy said they became aware of it in the – in 2012.¹⁵

...

Q: So that you understand, though, my question is, do you know that when the New England District Office of the FDA got the cease and desist order in May of 2011, they did not send it on to the Massachusetts Board of Registration in Pharmacy?

...

¹³ A 37-minute "highlight" video, documenting the "top ten" list below, is attached as Exhibit 1. The entire deposition video is attached as Exhibits 2, 3, and 4. These videos will be mailed to the Court Clerk, Counsel for the PSC, and other parties to be served.

¹⁴ David A. Kessler, MD Deposition Transcript is attached as Exhibit 5. The PSC's counsel's objections have been omitted in the text of this Memorandum of Law, but are shown in the transcript.

¹⁵ Kessler Dep. 266:3-11.

A: Let me check so we're actually clear, and we can put this on the record, if you like. The answer is in Exhibit 1237 that you marked. Let me just see. Let me just read you exactly what we -- what I know, and it's only based on what Dr. Hamburg and what Dr. Smith testified. You know, in retrospect -- this is Dr. Hamburg -- clearly I would have hoped that there would have been greater communication that speaks to the issue that was raised about ensuring the appropriate level ... that speaks to the issue that was raised about ensuring the appropriate level of back-and-forth communication and coordination with our state partners. When this email was received, it was in the context of a violation of state pharmacy registration and licensure. And while there was an indication they had sent the product in the absence of patient-specific prescriptions, there was no indication of a safety or quality concern that was being raised. So, you know, we really felt that it was, as I understand it, those kinds of issues are often handled state Board of Pharmacy to state Board of Pharmacy. We should have made sure that Massachusetts was aware.¹⁶

2.

Q: Now, as of December of 2007, were compounders permitted to make new drugs and skip registration with the FDA?

...

A: I don't understand your question.

Q: Could a compounder make new drugs whenever they wished and in whatever volumes they wished?

A: The new drug is a -- is a provision of the act. I'm not sure, again --

Q: Could a compounder make a new drug and sell it in interstate commerce without seeking approval from the FDA in advance?

A: This is -- let's define new drug, as this is -- in this case, this is a -- this is a -- a copy of an approved drug. This is a different drug. If this is a different drug, not a copy, essentially not a copy, right, you -- I mean, your question -- I mean, is it --

Q: It's not my question, it's the comment by Bruce Ota. If Bruce Ota with the FDA is right, did NECC have the prerogative to make new drugs and sell them in interstate commerce if they wished to do so?

A: Either you are a compounder, right? And a compounder -- if you are under FDAMA, if that was the law, or you are exempt from new drugs. So you can't be a compounder and be subject to the new drug provisions, right? Now let me look and see what the actual product is that's being sold here, and maybe that will shed light on what Mr. Ota is saying, right? So

¹⁶ *Id.* at 267:4-268:10.

this is New Orleans. This is actually – hold on a second. Okay. So this doesn't – I apologize. You gave me this case in December of 2007. This is April 2008.¹⁷

3.

Q: Question: From and after 2002, did the FDA take any steps to see which compounders were actually making large quantities of compounded products that they were shipping into interstate commerce?

A: So you're – you've misstated the record.

Q: It's not a statement of the record, Dr. Kessler – wait a minute – it is a question that deserves an answer.

A: Right. So FDA cited in this policy, as you and I went through, right, that the agency will consider whether a pharmacy engages in any of the following acts. And it lists 1 through 9. You read me a statement that was a factual question, right, under discussion. You implied, in that question, or I understood, that one of the criteria was an inordinate amount of 1 through 9. What I stated on number 1 was where I saw limited quantities had to do with limited quantities in relation to the amounts of drugs compounded after receiving valid prescriptions. So again, the essential issue here is, I mean, are there prescriptions, right? And the amounts that you're compounding with regard to that amount of prescriptions you have, that's the issue here.¹⁸

4.

Q: Now, remember what I wanted to know about was if, as the FDA said, this appeared to be a new drug, did the FDA have the responsibility to take some action?

...

A: Hold on a second. You can see that there's considerable investigation here of this doctor.

Q: That's not responsive.

A: I understand.

Q: And I object to it. It's not responsive.

A: Okay.

¹⁷ *Id.* at 293:1-294:10.

¹⁸ *Id.* at 260:13-261:13.

Q: There's a pending question. Did FDA have an obligation to take some action if they thought, as Bruce Ota communicated, that NECC was making a new drug and selling it in interstate commerce?

...

A: Depends what a general counsel of the agency thought the law was. And as you've seen, there is questions about that.¹⁹

5.

Q: Why didn't they take the time to check and see if this volume of product was covered by patient-specific prescriptions?

...

A: Exactly the answer I gave you before when you cut me off. I gave you an answer.

Q: I –

A: Yes, you did.

Q: Okay. What is the answer, then?

A: Read back what my answer was. What I said was the reason – what FDA was doing at this time, right, was what FDA should have been focused on, which was to – and what its clear authority was, certainly with FDAMA – if the product was contaminated, FDA had a responsibility to get that product off the market and get that product recalled. That's what FDA did. Okay? The state Board of Pharmacy – I mean, yes, you are right, I very much wish, okay, that this whole scheme that your client and the – and NECC were engaged in were – was discovered and exposed. That would have been very nice. That – being able to show that there was this scheme of providing prescriptions or prescription order forms or lists when that was the key safeguard, and NECC was doing this without, your client was facilitating, do I wish that that would have been uncovered? Absolutely. It was not.²⁰

6.

Q: And the volume shown on the two letters is a volume that is inordinate for a retail pharmacy, is it not?

...

A: So the statute – what the statute says – let me finish, sir. What the compliance policy guide says, okay, to the provision that we've talked about on limited use, the issue is it would be – the limited use, okay, depends on the number of prescriptions that the company had. So what the compliance policy guide is very clear about, compounding drugs in anticipation, except in very limited instances –

¹⁹ *Id.* at 301:11-302:6.

²⁰ *Id.* at 208:14-209:15.

Q: No, it says quantities.

A: Very limited quantities in relation to the amount of drugs compounded after receiving valid prescriptions.

Q: Okay.

A: So the concept here is it is – if you have – this all determines, this all hangs on the central premise of whether there were prescriptions here.²¹

7.

Q: Now, when you put these two together, doesn't this show to you that NECC, at the time, was making a large quantity of preservative-free drug products analogous to manufacturing?

...
A: If you're preservative free and you are emphasizing preservative free, that's not a compound – that's not a drug that's commercially available, right? If it's not a drug that's commercially available, okay, you have to meet – you're either a compounder or a manufacturer. We know – there's no doubt that on February 24th, 2003, right, Massachusetts Board of Pharmacy and FDA concluded, right, that it was decided the current findings supported a compounding role for NECC. That was FDA. That's what we know in this time period. So on the basis of what everything FDA had, which was the compliance policy guide, it had all the facts, these letters, right, certainly by – within that – you know, a 12-month period, the FDA concluded, through this whole episode, that it was a compounder.²²

8.

Q: Okay. Well, what's the definition of a manufacturer?

...
A: Under what purposes? For what purposes?

Q: What is the definition of a manufacturer to making large volumes of drugs?

...
A: So, I mean, our entire – our entire legitimate drug supply, I mean, in this country is, you know, Pfizer and Abbott. Those are manufacturers. They don't need physician – patient-specific practices. They are introducing a drug in interstate commerce, right, for sale, and they are subject to 505, right? They are clearly manufacturers.

Q: Okay. I know that Pfizer is a manufacturer and I know Abbott is a manufacturer. What I want you to do, though, is tell us what is the

²¹ *Id.* at 179:14-180:9.

²² *Id.* at 194:8-195:4.

definition of a manufacturer. Don't just tell me a company name. That's not helpful. Tell me what the definition is.

...

A: Under FDAMA or not under FDAMA?

Q: The Food, Drug and Cosmetic Act of 1938, as amended, up to and including but not including the 1997 FDAMA.

A: Not including –

Q: Not including FDAMA.

...

A: So if you wanted to do that, that's what I wrote specifically in the – that's what we wrote specifically in the 1992, 1994 compliance policy guide.

Q: What is it?

A: Okay. And it gave certain – that gave certain criteria, okay, that if you were engaged in – they were not – they were, I don't know, seven, eight, nine criteria that were part of that policy guide whereby even if you were a retail pharmacy, the agency would not grant enforcement discretion.²³

9.

Q: Was FDA entitled to rely upon the representations by NECC?

...

A: I see no statutory prohibition against that.

Q: I asked you a question. In terms of enforcement, was FDA entitled to rely upon the representation by NECC that all of these drugs, you say, were covered by patient-specific prescriptions?

A: I didn't say these –

...

A: -- these drugs were covered by patient prescriptions. Please understand, there was a scheme here, right?

Q: In 2002 is the time frame we are talking about.

A: Well –

Q: That's what we're talking about.

A: So I don't see the data from 2002. The data that I – sorry. Let me be very clear. There is a statement, okay, in direct questions, I mean, that

²³ *Id.* at 196:6-198:1.

NECC represents in 2002 that they dispense approved product in bulk for administration to individual patients pursuant to receipt of a valid prescription from a prescriber.

Q: And that's why I asked you, and we've spent ten minutes on this, was FDA entitled to rely upon that representation by NECC? It's a simple question.

A: It's not.

...

A: It's naïve, sir.

...

A: With all due respect, it can't be simple. What do you mean "entitled" – you are a sophisticated lawyer. What do you mean "entitled" by?²⁴

10.

Q: Did Barry Cadden or Bob Ronzio have the authority to waive the requirement for patient-specific prescriptions?

A: Patient prescription –

...

A: Patient-specific prescriptions were essential if you were going to order – deliver prescription compounded drugs.

Q: My question again: Did Barry Cadden, Robert Ronzio, or anybody at NECC have the authority to waive the requirement for patient-specific prescriptions?

...

A: I think my answer is the exact same answer that I gave you before, and I'm trying to pull it up. Give me a second.

Q: What is it?

...

A: Let me give you – pull up my – Can you help me get to the bottom? I guess – is there – thank you. Wait. My – my answer –

Q: The screen in front of you is a copy of the transcription by the court reporter to your left, isn't it?

A: Yes. And I just want to read. My answer was patient-specific prescriptions were essential if you were going to order or deliver prescription compounded drugs.

Q: Okay.

²⁴ *Id.* at 202:25-204:11.

A: So they were essential.

Q: Okay. I know they're essential according to you, but my question –

A: It's not just according to me. It's according to – should be according to any definition of compounding that you could read or exists.

Q: The question is, did Barry Cadden, Robert Ronzio, Doug Conigliaro, or anybody at NECC have the authority to waive patient-specific prescriptions?

A: Pursuant to what?

Q: Any authority. Did they have the authority –

A: Pursuant to federal law?

Q: State law. Federal law.

A: There was a –

...

A: There was a requirement – excuse me.

Q: Could you start that again, because it wasn't clear.

A: There is a requirement, right, as I said, that if you are going to order or you're going to deliver compounded drugs, you have to have a patient-specific prescription.

Q: Okay. So did Barry Cadden have the authority to waive that requirement?

A: Barry –

...

A: -- Cadden did not have the authority to waive that requirement, nor did STOPNC have the authority to submit false names.²⁵

The excerpts demonstrate Dr. Kessler's refusal to provide a direct, responsive answer to Defendants' counsel's questions. Fed. R. Civ. P. 37 requires the Court to treat Dr. Kessler's evasive answers as a *failure to answer* the Defendants' questions. The Defendants move the Court to compel completion of the deposition of David

²⁵ *Id.* at 225:8-227:17.

Kessler, MD, mandating direct, punctual answers, at the PSC's expense. By impeding and foreclosing completion of his examination, Dr. Kessler's conduct warrants additional time.²⁶

PSC COUNSEL'S MISCONDUCT

Counsel for the PSC²⁷ never advised Dr. Kessler to provide direct, responsive answers to any of the Defendants' questions. Counsel for the PSC repeatedly objected to Defendants' counsel's²⁸ questions on multiple grounds: asked and answered; argumentative; and misleading. In fact, counsel for the PSC explicitly disagreed with Defendants' counsel's assertion that Dr. Kessler's answers were nonresponsive:

Mr. Gideon: Oh, my gosh. This is just ridiculous. You guys would have to recognize – I think anybody would – that his answers have been consistently nonresponsive, almost from the beginning –

Mr. Arbitblit: I absolutely disagree.

Mr. Gideon: Let me finish. – almost from the beginning. If you ask him if today is Friday, he gives us a description of the entire calendar. It has been nonresponsive all day long. And I asked him a simple question if anybody had ever given him the Penta exhibits where the FDA describes NECC as a manufacturer, and he just starts talking, and then you defend him. It's ridiculous.

Mr. Arbitblit: That is so far from a simple question, Counsel, because it's includes references to a document that you haven't shown the witness that may or may not be consistent with what you are representing. You don't have the right to represent a document out of thousands of pages reviewed and pretend that you are all knowledgeable as to what's in it, or that he has no right to see it to answer a question. And he certainly was answering your questions all day long.²⁹

²⁶ See Fed. R. Civ. P. 30(d)(1).

²⁷ Don C. Arbitblit and Mark P. Chalos of Lieff, Cabraser, Heimann & Bernstein appeared on behalf of the PSC and Dr. Kessler.

²⁸ C.J. Gideon, Jr. examined Dr. Kessler on behalf of the Tennessee Clinic Defendants. Kaycee L. Weeter appeared with Mr. Gideon on behalf of the Tennessee Clinic Defendants.

²⁹ Kessler Dep. 166:17-167:15 (emphasis added).

Counsel for the PSC took no responsibility for Dr. Kessler's evasive and nonresponsive conduct. In fact, counsel for the PSC attributed Defendants' counsel's examination difficulties to the *Defendants' questions*:

Mr. Chalos: C.J., you are not going to get anywhere – excuse me. You're not going to get anywhere acting that way. You are frustrated, I get it, but it's because of your questions.³⁰

Counsel for the PSC only directed Dr. Kessler to not answer when Dr. Kessler expressed a willingness to speak without a question pending.³¹ Counsel for the PSC allowed Dr. Kessler to be evasive and unresponsive throughout his seven (7) hour deposition. Their silent endorsement and ratification of Dr. Kessler's misconduct is the functional equivalent of advising his misconduct. Counsel for the PSC, too, impeded, delayed, and frustrated the fair examination of Dr. Kessler. Sanctions are warranted.

SANCTIONS

With this Motion to Compel, the Defendants move the Court to impose the following sanctions on the witness and the PSC:

1. Require the witness and the PSC to absorb the costs associated with the initial effort to take Dr. Kessler's deposition, including Dr. Kessler's \$1,000 per hour fee and the fees of the court stenographer and videographer; and
2. Require Dr. Kessler to return for completion of his deposition, providing direct, responsive, succinct answers to each question.

³⁰ *Id.* at 235:6-9 (emphasis added).

³¹ See e.g., Kessler Dep. 214:6-7; 279:16-280:10.

CONCLUSION

The Tennessee Clinic Defendants respectfully request this Court enter an order compelling Dr. Kessler to present himself to complete his deposition, and to provide direct, responsive, succinct answers throughout the second chapter of his deposition, with the costs of the first setting borne by the witness and the PSC. Dr. Kessler's evasive and nonresponsive misconduct throughout his deposition significantly impeded, delayed, and frustrated the Defendants' fair examination of him. Counsel for the PSC's failure to curb Dr. Kessler's evasive and nonresponsive misconduct was the functional equivalent of advising Dr. Kessler's misconduct. The sanctions sought are warranted.

LOCAL RULE 37.1

Pursuant to Local Rule 37.1, the Tennessee Clinic Defendants have made a good-faith effort to resolve this dispute, without success. On March 8, 2016, counsel for the Defendants e-mailed counsel for the PSC asking them to agree to grant the Defendants additional time to depose Dr. Kessler. Counsel for the PSC did not agree.³²

Respectfully submitted,

GIDEON, COOPER & ESSARY, PLC

/s/ Chris J. Tardio

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³² Correspondence attached as Exhibit 6.

***Attorneys for the Tennessee Clinic
Defendants***

* Admitted pursuant to MDL Order No. 1.

** Admitted *pro hac vice*.

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the CM/ECF system will be served electronically to the registered participants identified on the Notice of Electronic Filing and copies will be e-mailed or mailed via regular U.S. mail to those participants identified as unregistered this 29th day of March, 2016.

/s/ Chris J. Tardio

Chris J. Tardio